NEW JERSEY DEPARTMENT OF HEALTH & SENIOR SERVICES
HUMAN RESEARCH ETHICS PROGRAM

EXTRAMURAL IRB APPLICATION SUBMISSION FLOWCHART

STEP 1

PRINCIPAL INVESTIGATOR

Items to be Submitted to DHSS Employee Responsible for the Requested Data:

- IRB Checklist (OC-40)
- Assurance for the Ethical Conduct of Research (OC-41)
- IRB application
- Protocol
- Consent/Assent Forms
- Recruitment Materials
- Instruments
- Grant or Contract
- Curriculum Vitas
- Institutional Certification of Research Ethics Training

Recommendation:
Contact the DHSS Program responsible for the data being requested for research. It is also advised that you consult HREP personnel who will provide guidance on submitting an IRB application.

OC-39

STEP 2

DHSS PROGRAM SUPERVISOR

Responsibilities:

Review IRB application materials to determine if: 1) the project is scientifically valid, 2) relevant to DHSS' mission and 3) the project is permissible. The DHSS' Program Supervisor certifies these elements by signing form OC-39 and sending the IRB application materials to their Assistant or Deputy Commissioner.

OC-39

STEP 3

DHSS DIVISION ASSISTANT/DEPUTY COMMISSIONER

Responsibilities:

Review IRB application materials to determine if: 1) the project is scientifically valid, 2) relevant to DHSS' mission and 3) the project is permissible. The DHSS Division Assistant/Deputy Commissioner certifies these elements by signing form OC-39 and sending the IRB application materials to HREP.

OC-39

STEP 4

DHSS HUMAN RESEARCH ETHICS PROGRAM

Responsibilities:

Review IRB application materials for completeness and conduct an Ethics & Regulatory Assessment. HREP personnel will work directly with the Principal Investigator to address and resolve any ethical or regulatory issues. Upon approval HREP will submit the completed IRB Application to the Department's IRB.

*The IRB will only accept IRB applications submitted from HREP with an HREP certification letter.